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Subject: NEWS UPDATES: EPA Advisors Raise Concerns Over IRIS Program Review's 'Moving Target' (Inside EPA)
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EPA Advisors Raise Concerns Over IRIS Program Review's 'Moving Target'

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The head of a National Research Council (NRC) panel tasked with reviewing EPA's Integrated Risk Information System (IRIS) program is raising concerns over how the group can make recommendations on improving the process at the same time the agency is already implementing its own changes to the risk assessment program.

"I think the challenge for us would be if you are continually revolutionary . . . we will have a moving target in front of us," Jonathan Samet, a professor at the University of Southern California Keck School of Medicine and chair of the NRC's panel tasked with a "Review of Revisions to the IRIS Process," told EPA officials during a Dec. 18 meeting in Irvine, CA.

Given that the panel is tasked with providing comments on "where you are going . . . we are going to have to make sure we know where you're going, and so you need to know where you're going" with changes to the program, Samet added.

NRC is currently reviewing EPA's IRIS program following congressional concerns that stemmed from 2011 NRC findings that charged EPA's draft IRIS assessment for formaldehyde failed to justify its conclusion that the chemical poses leukemia risks and called for a host of reforms to the program. As a result House appropriators required NRC to review the agency's assessments for arsenic, which is in the very early phases, and two other chemicals -- although EPA and NRC later agreed to combine those into a review of the program as a whole that would include recommendations for improvements.

However, EPA has been making changes to the IRIS program following the 2011 NRC recommendations and similar complaints from industry and Republicans, and has implemented some of the recommendations.

During the Dec. 18 meeting, Vince Cogliano, head of the IRIS program, told the NRC panel that the agency is "adopting all of the recommendations made in the NRC review of formaldehyde" and has already made headway on several, including better documenting literature searches that are organized by health effects; easier to read documents; the implementation of chemical assessment support teams to ensure standards and consistency among documents; the creation and use of guidance documents; and greater public dialogue and review.

Additionally, Lynn Flowers, associate director of EPA's National Center for Environmental Assessment, told the NRC panel the agency is working to improve the way it assesses the adverse effects of chemicals. These actions include standardizing approaches for evaluating data and development of exposure response arrays, as well as creating more systematic, robust and transparent synthesis and integration of data indicating which factors are most influential.

In the long term, EPA plans to "develop of a weight of evidence /data integration system with standardized language for effects other than cancer," according to Flowers' presentation, although she added the process for how to do that "is still something that has to be worked out."

The agency also has committed to reducing the number of assessments in process at one time, and speeding up the process to complete most assessments to 11.5 to 23 months.

A lot of the changes will be apparent when the agency releases its assessment of benzo[a]pyrene, the first IRIS assessment completed under the new system, in the coming months, Cogliano added. That assessment will be an early example, with later ones becoming "more sophisticated," Cogliano said. "Some implementation [of the changes] is going to be chemical by chemical."

But the ever-changing nature of the IRIS program presents problems for the NRC panel, which is specifically tasked with reviewing "the IRIS process and the changes being implemented or planned by EPA and will recommend modifications or additional changes as appropriate to improve the scientific and technical performance of the IRIS program . . . the committee will review current methods for evidence-based reviews and recommend approaches for weighing scientific evidence for chemical hazard and dose-response assessments," according to the project's website.

Samet told EPA officials, "We are going to come to some point and evaluate where you've come . . . You're doing an awful lot of work and it seems like literally every aspect of the IRIS assessment process" is changing.

"I think we will have to assess together where it is that our review stops on what what you are doing, and starts on what you could do," Samet said.

EPA in its efforts to implement the IRIS program recommendations from the NRC formaldehyde review has run into similar problems, with officials concerned that plans for a pending weight-of-evidence workshop in summer 2013 may conflict with an NRC effort to host a similar event in the spring as part of its review.

While the agency had said its weight-of-evidence workshop would look at the issue as it applies to all parts of IRIS assessments, in July Cogliano referenced the workshop as focused on non-cancer issues only.

"We're going to have a workshop to look at various weight-of-evidence non-cancer schemes," Cogliano told those attending the listening session. "We will work on weight of evidence over the coming year. We will coordinate with [NRC]. We'll try to do something complimentary, but also allow us to get more [confident] weight-of-evidence assessments." -- *Jenny Hopkinson*

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